IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

DAVID BRENDEL and ROSINA BRENDEL, Plaintiffs, v. **DAVOL, INC.,** and **C. R. BARD INC.,** Defendants.	Cause No: PERSONAL INJURY/ PRODUCT LIABILITY JURY TRIAL DEMANDED

COMPLAINT

COME NOW, Plaintiffs David Brendel and Rosina Brendel ("Plaintiffs") and by and through their attorneys, allege the following upon information and belief:

Parties

1. Plaintiffs David Brendel and Rosina Brendel are citizens and residents of St. Louis City, Missouri.

2. Defendant Davol Inc. ("Davol") is a corporation that is incorporated under the laws of the State of Rhode Island. Davol has its principal place of business in the State of Rhode Island. It manufactures the Ventralex Hernia Patch ("Hernia Patch") at 100 Sockanosset Crossroad, Cranston, Rhode Island. Davol has a registered agent in Rhode Island at CT Corporation System, 10 Weybosset St., Providence, Rhode Island. Davol focuses its business on products in key surgical specialties, including hernia repair, hemostasis, orthopedics, and laparoscopy. Davol at all times relevant did substantial and continuous business in the State of Missouri.

3. Defendant C. R. Bard Inc. ("Bard") is a corporation that is incorporated under the laws of the State of New Jersey. It is the corporate parent/stockholder of Davol and participates in the manufacture and distribution of the Bard Ventralex Hernia Patch. It also manufactures and supplies Davol with material that forms part of the Bard Ventralex Hernia Patch. Bard at all times relevant did substantial and continuous business in the State of Missouri.

Jurisdiction and Venue

4. This court has diversity jurisdiction over the parties pursuant to 28 U.S.C. §1332(a). Plaintiffs and no defendant are citizens of the same state as Plaintiffs and the amount in controversy exceeds $75,000, exclusive of interest and costs.

5. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391(c) because Defendants are corporations. A corporation is deemed to reside in any judicial district where its contacts would be sufficient to subject it to personal jurisdiction at the time the action is commenced. Defendants distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, physicians, hospitals and medical practitioners at all times relevant and including the day this action is commenced, certain hernia surgical repair products to be surgically implanted in patients in the state of Missouri, and more particularly within the jurisdiction boundaries of the United States District Court for the Eastern District of Missouri.

General allegations

The Ventralex Hernia Patch

6. The Ventralex Hernia Patch is used to repair ventral hernias, or hernias of the abdominal region. The Ventralex Hernia Patch is made of two pieces of mesh that

surround a flexible plastic ring. The surgeon places the mesh patch in a small incision. The surgeon folds the patch and places it at the site of the hernia. The released ring is then designed to spring back into its original shape, flattening the patch. The mesh-like material serves as a substrate, allowing the hernia patient's own tissue to grow and assist in healing the hernia.

7. The Ventralex Hernia Patch is manufactured by Defendant Bard and their subsidiary, Defendant Davol, which owns the patent on the device.

8. The Defendants Bard and Davol (collectively "Defendants") submitted their 510k Application to the Federal Drug Administration (hereinafter referred to as the "FDA") on July 16, 2002. Following this 510k Application the Ventralex Hernia Patch was authorized by the FDA as a Class II medical device.

9. Soon after the Ventralex Hernia Patches were placed on the market, Defendants began receiving actual notices of Ventralex Hernia Patch defects and failures. Not only was there no device history record (DHR) review performed—as called for by protocol—but also Defendants actively and intentionally concealed these notices concerning the defective and dangerous condition associated with the Ventralex Hernia Patches from Mr. Brendel, Mr. Brendel's physicians, and the general public.

10. After the defective and dangerous Ventralex Hernia Patch was already placed on the market, Defendants conducted physician screenings and reviews. According to protocol, these surveys and reviews were needed before placing the device on the open market. Furthermore, an Establishment Inspection Report ("EIR") conducted by the FDA in 2006 found that the post market survey validation process of the device was incomplete and failed to include all the data from the physicians surveyed during this

time. Whether intentionally or negligently, Defendants failed to properly conduct and monitor their own post market design validation physician surveys including those which demonstrated unfavorable or "dissatisfied" results. Defendants actively and intentionally withheld these complaints and concerns of the physician surveyors from Mr. Brendel, Mr. Brendel's surgeons, and the public at large.

11. During the spring and summer period of 2005, there was a substantial increase in the number of complaints with defendants various hernia mesh patches, including the Ventralex. Defendants' corporate executives were notified and thus made aware of these complaints. Nevertheless, in spite of their knowledge of increasing complaints and complications, Defendants waited until August 30, 2005 to initiate a partial hernia patch manufacturing hold, and it was not until December 8, 2005 that the Defendants finally commenced a distribution hold. (Defendants have since admitted that these product quality hold and release procedures were not applied on a timely basis.) Furthermore, Defendants actively and intentionally chose not to immediately inform Mr. Brendel, Mr. Brendel's physicians, the FDA, and all other individuals who had been implanted or would be implanted with their hernia mesh patches of the numerous complaints and complications they were on notice of, nor of the holds in effect.

12. On December 22, 2005, Davol recalled many sizes of its hernia patches under a Class I recall notice. An FDA Class I recall is issued for problems related to medical devices that are potentially life threatening or could cause a serious risk to the health of the patients implanted with the devices. Mr. Brendel was given no notice of this Ventralex Hernia Patch recall.

13. The FDA conducted the aforementioned EIR investigations in January and

February of 2006. The results of these investigations determined, among other things, that Defendants:

a. had excluded ring failure events which should have been included from their complication database, reports, and recall notices;

b. misidentified numerous hernia patch complication events;

c. failed to apply the product quality hold and release procedure on a timely basis;

d. failed to properly follow the procedures for conducting design validation review;

e. failed to identify all the actions necessary to correct and prevent the recurrence of further ring break and hernia patch complications; specifically, they provided no justification for including only the Extra Large Kugel Mesh Patch sizes in the December 2005 recall;

f. failed to provide full information which they knew regarding numerous Ventralex Hernia Patch complaints;

g. failed to actually perform strength testing on memory recoil rings for Ventralex Hernia Patch before putting them into the stream of commerce;

h. failed to maintain appropriate sources for quality data to identify, track, and trend existing and potential causes for the ring failures and Ventralex Hernia Patch complaints resulting in numerous inconsistencies and errors in the raw data and from the actual complaints and what was placed in the electronic databases.

14. On March 24, 2006, the initial Class I recall on Defendants' Kugel Hernia Mesh Patches was expanded to include several more sizes of the patch and numerous additional lots of the defective hernia mesh product.

15. On January 10, 2007, the existing recall on the Defendants' Kugel Mesh Patches was again expanded to encompass further production lots of the defective hernia mesh product. As of that date, the total number of recalled Kugel Mesh Hernia Patches that were distributed amounted to more than 100,000 units.

Plaintiff's injuries caused by the Kugel hernia mesh patch

16. On August 25, 2006, Plaintiff David Brendel underwent a ventral incisional hernia repair surgery at St. Mary's Hospital in St. Louis, Missouri. Mr. Brendel's hernia was repaired with a Bard Ventralex Hernia Patch and he recovered from the surgery.

17. The Ventralex Hernia Patch implanted in Mr. Brendel was designed, manufactured, sold and distributed by Defendants to be used by surgeons for ventral hernia repair surgeries and was further represented by Defendants to be an appropriate, cost-effective and suitable product for such purpose.

18. At the time of his operation, Mr. Brendel was not informed of, and had no knowledge of, the complaints, known complications and risks associated with the Ventralex Hernia Patch, nor was Mr. Brendel on notice that the Ventralex Hernia Patch that was inserted into his body was to be recalled.

19. In November 2008, Mr. Brendel began experiencing severe abdominal pain with burning and stinging. On January 6, 2009, he underwent a repair of his ventral hernia with Bard Ventralex mesh at St. Anthony's Medical Center, St. Louis, Missouri. .

20. In July 2009, Mr. Brendel again began experiencing severe abdominal pain and his physician recommended laparoscopic repair of the hernia mesh. On November 2, 2010, he underwent surgery for ventral hernia repair at St. Mary's Hospital, St. Louis, Missouri. During the surgery, it was discovered that the Ventralex Hernia Patch had buckled and "was folded over on itself". The hernia mesh patch had to be "tacked up in place also with the Pro tacker".

21. Mr. Brendel subsequently endured a painful and protracted recovery process during which his activities were restricted and he was unable to lift heavy objects.

22. Because of the defective Ventralex Hernia Patch and all the medical visits and surgeries it necessitated, Mr. Brendel has suffered and will continue to suffer physical pain and mental anguish.

23. Mr. Brendel has also incurred substantial medical bills and has suffered loss of other monies due to the defective Ventralex Hernia Patch that was implanted in his body.

24. Upon information and belief, Defendants failed to comply with the FDA application and reporting requirements.

25. Upon information and belief, Defendants were aware of the high degree of complication and failure rate associated with their Ventralex Hernia Patch before it was recalled.

26. Upon information and belief, Defendants were aware of the defect in manufacture and design prior to the recall of their Ventralex Hernia Patch.

27. Upon information and belief, the complications and failures associated with their hernia mesh patches, including the Ventralex Hernia Patches, are not limited to the sizes which Defendants have already recalled.

28. Upon information and belief, Defendants were aware of the defects in the manufacture and design of the non-recalled hernia mesh patches, including the Ventralex Hernia Patch, and chose not to issue a recall on all hernia mesh patches in the face of the high degree of complication and failure rates.

29. Upon information and belief, the complications and failures associated with their hernia mesh patches, including the Ventralex Hernia Patches, are not limited to the sizes which Defendants have already recalled.

30. Upon information and belief, Defendants were aware of the defects in the manufacture and design of the non-recalled hernia mesh patches, including the Ventralex Hernia Patch, and chose not to issue a recall on all Ventralex Hernia Patches in the face of the high degree of complication and failure rates.

COUNT I

(Strict Liability - Design Defect)

31. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

32. Defendants are strictly liable to Plaintiffs in the following respects:

a. Defendants designed, manufactured, assembled, distributed, conveyed, supplied and/or sold the Ventralex Hernia Patch for hernia repair surgery in the course of their business;

b. Defendants' Ventralex Hernia Patch was in a defective condition unreasonably dangerous because it failed to perform safely and effectively for the purpose it was originally designed. When implanted in Mr. Brendel's body, the memory recoil ring ("PET" coil ring) buckled, causing him to develop serious physical injuries;

c. Defendants' Ventralex Hernia Patch was used in a manner reasonably anticipated because it was implanted by the surgeon in Mr. Brendel's body to repair a hernia; and

d. Mr. Brendel was damaged as a direct result of the defective condition that existed when the Ventralex Hernia Patch left the possession of Defendants.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT II

(Strict Liability - Failure to Warn)

33. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

34. Defendants are strictly liable for failing to warn Mr. Brendel in the following respects:

a. Defendants, in the course of their business, sold the Ventralex Hernia Patch to Mercy Hospital in Council Bluffs, Iowa for hernia repair surgeries;

b. the Ventralex Hernia Patch was in a defective condition unreasonably dangerous when put to a reasonably anticipated use due to the propensity of the memory recoil ring ("PET coil ring") to fail when the Ventralex Hernia Patch was implanted in Mr. Brendel body;

c. Defendants did not give adequate warning of the danger that the memory recoil ring ("PET coil ring") would fail;

d. the Ventralex Hernia Patch was used in a manner reasonably anticipated because it was implanted by the surgeon in Mr. Brendel's body to repair a hernia; and

e. Mr. Brendel was damaged as a direct result of the Ventralex Hernia Patch being sold without Defendants providing warning, labels or instructions regarding the Ventralex Hernia Patch's dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT III

(Negligent Design)

35. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

36. Defendants were negligent in designing the Ventralex Hernia Patch that was implanted in Mr. Brendel's body in the following respects:

a. Defendants designed and manufactured the Ventralex Hernia Patch which was implanted in Mr. Brendel's body;

b. the Ventralex Hernia Patch, as designed by Defendants, had a specific latent defect because the memory recoil ring (or "PET coil ring") was subject to breaking or fragmenting when implanted in Mr. Brendel's body;

c. Defendants failed to use ordinary care in designing the Ventralex Hernia Patch to be reasonably safe when implanted in Mr. Brendel's body because a reasonably prudent manufacturer of hernia mesh patches knew or should have known that the memory recoil ring (or "PET coil ring") in the Ventralex Hernia Patch as designed would fail prematurely when implanted in Mr. Brendel's body; and

d. Mr. Brendel sustained injuries and damages as a direct result of Defendants' negligent design of the Ventralex Hernia Patch.

37. Defendants negligently and carelessly designed the Ventralex Hernia Patch in that it was dangerous and unsafe for the use and purpose for which it was intended.

38. Defendants breached their duty by failing to comply with state and federal regulations concerning the design of the Ventralex Hernia Patch.

39. As a direct and proximate result of the duties breached, the Ventralex Hernia Patch used in Mr. Brendel's hernia repair surgery failed, resulting in Mr. Brendel suffering pain and harm.

40. As a direct and proximate result of Defendants' negligence, Mr. Brendel has suffered injuries and damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT IV

(Negligent Failure to Warn)

41. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

42. Defendants were negligent in failing to warn Mr. Brendel of hazards of the Ventralex Hernia Patch in the following respects:

a. in the course of their business, Defendants designed, manufactured and supplied the Ventralex Hernia Patch to for use in Mr. Brendel's hernia repair surgeries at St. Anthony's Medical Center, St. Louis, Missouri and St. Mary's Hospital in St. Louis, Missouri;

b. the Ventralex Hernia Patch, as designed by Defendants, had a specific latent defect when put to reasonably expected use because the memory recoil ring (or "PET coil ring") was subject to breaking or fragmenting when implanted;

c. Defendants had no reason to believe that Mr. Brendel would realize the danger posed by the latent defect in the Ventralex Hernia Patch and Mr. Brendel did not know at the time of use of the Ventralex Hernia Patch, nor at any time prior, of the existence of the defect in the Ventralex Hernia Patch; and

d. Defendants knew, or by using ordinary care, should have known of the dangerous condition of the Ventralex Hernia Patch; and

e. Defendants did not warn of the danger to Mr. Brendel because Defendants failed to provide a warning, labels or instructions regarding the Ventralex Hernia Patch's dangerous propensities that were known or reasonably scientifically knowable at the time of distribution.

43. Mr. Brendel suffered the aforementioned injuries and damages as a direct result of Defendants' failure to warn.

44. The conduct of Defendants in continuing to market, promote, sell and distribute the Ventralex Hernia Patch after obtaining knowledge that the patches were failing and not performing as represented and intended, showed a complete indifference to or conscious disregard for the safety of others, justifying an award in such sum which will serve to deter Defendants and others from similar conduct.

45. In addition, Defendants failed to warn of the known or knowable injuries associated with malfunction of the Ventralex Hernia Patch, including but not limited to ring buckling, ring migration through the abdominal wall; abscesses; bowel obstruction

and sepsis; and chronic intestinal fistulae (abnormal connections or passageways between the intestines and other organs).

46. Mr. Brendel suffered injuries and damages as a direct result of Defendants' negligence in failing to warn.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT V

(Negligence)

47. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

48. Defendants were negligent to Mr. Brendel in the following respects:

a. Defendants at all times mentioned had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings, and prepare for use, the Ventralex Hernia Patch;

b. Defendants at all times mentioned knew or in the exercise of reasonable care should have known, that the Ventralex Hernia Patch was of such a nature that it was not properly manufactured, tested, inspected, packaged, labeled,

distributed, marketed, examined, sold, supplied, prepared and/or provided with the proper warnings, and posed an unreasonable likelihood of injury to the Ventralex Hernia Patch users;

c. Defendants so negligently and carelessly designed, manufactured, tested, failed to test, inspected, failed to inspect, packaged, labeled, distributed, recommended, displayed, sold, examined, failed to examine and supplied the Ventralex Hernia Patch, that it was unreasonably dangerous and unsafe for the use and purpose for which it was intended;

d. Defendants were aware of the probable consequences of the Kugel Patch in that Defendants knew or should have known the Ventralex Hernia Patch would cause serious injury; and

e. Defendants failed to disclose the known or knowable risks associated with the Ventralex Hernia Patch.

49. Furthermore, Defendants willfully and deliberately failed to avoid those consequences, and in doing so, Defendants acted in conscious disregard of the safety of Mr. Brendel.

50. Defendants owed a duty to Mr. Brendel to adequately warn him and his treating physicians of the risks of breakage, separation, tearing and splitting associated with the Ventralex Hernia Patch and the resulting harm and risk it would cause patients.

51. Defendants breached their duty by failing to comply with state and federal regulations concerning the study, testing, design, development, manufacture, inspection, production, advertisement, marketing, promotion, distribution, and/or sale of the Ventralex Hernia Patch.

52. As a direct and proximate result of the duties breached, the Ventralex Hernia Patch used in Mr. Brendel's hernia repair surgery failed, resulting in much pain and suffering, mental anguish, doctor visits, subsequent procedures, and substantial medical bills.

53. As a direct and proximate result of Defendants' negligence, Mr. Brendel suffered severe pain, injuries and damages.

54. Defendants' conduct in continuing to market, sell and distribute the Ventralex Hernia Patch after obtaining knowledge it was failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT VI

(Breach of Implied Warranty)

55. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

56. Defendants are liable to Mr. Brendel for their breach of implied warranty in the following respect:

a. Defendants manufactured, distributed and sold the Ventralex Hernia Patch that was implanted in Mr. Brendel;

b. Defendants impliedly warranted to Mr. Brendel, his physicians and health care providers that the Ventralex Hernia Patch was of merchantable quality and safe for the use for which it was intended;

c. Defendants knew or reasonably should have known that the Ventralex Hernia Patch at the time of sale was intended to be used for the purpose of surgical implantation into the body for hernia repair;

d. Mr. Brendel, his physicians, and his health care providers reasonably relied on Defendants' judgment, indications and statements that the Ventralex Hernia Patch was fit for such use; and

e. when the Ventralex Hernia Patch was distributed into the stream of commerce and sold by Defendants, it was unsafe for its intended use, and not of merchantable quality, as warranted by Defendants, in that it had very dangerous propensities when used as intended and implanted into a patient's body and, as a result, could cause serious injury of harm or death to the end user.

57. As a result of Defendants' conduct and actions, Mr. Brendel suffered such injuries and damages.

58. As such, Defendants breached the implied warranty of merchantability and are therefore liable to Mr. Brendel for the injuries she sustained and the costs she incurred as a result of using the defective Ventralex Hernia Patch.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT VII

(Fraud and Intentional Misrepresentation)

59. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

60. Defendants, through advertising, labeling, direct product detailing by sales representatives to the medical community, and other communications including letters to the medical community, and medical literature disseminated made misrepresentations to physicians and the public, including Mr. Brendel, about the safety and efficacy of the Ventralex Hernia Patch.

61. Defendants represented the Ventralex Hernia Patch to be safe to use. These were material misrepresentations of fact concerning the character, nature and dangerous propensities of the product manufactured, sold, and marketed by Defendants.

62. Physicians and their patients, including Mr. Brendel, justifiably relied on Defendants' misrepresentations, and Mr. Brendel was harmed as a result.

63. Mr. Brendel is entitled to recover damages for his injuries produced by Defendants' misrepresentations.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT XIII

(Loss of Consortium)

64. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

65. Plaintiff Rosina Brendel is, and at all times relevant hereto, has been the lawful spouse of Plaintiff David Brendel, and as such she is entitled to the comfort and enjoyment of his society and services.

66. As a direct and proximate result of the foregoing misconduct of the Defendants, Ms. Brendel has been deprived of her spouse's companionship, services, solace, consortium, affection and attention to which she is entitled.

67. As a result of the foregoing, Ms. Brendel has been and will continue to be injured and damaged.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT IX

(Violation of the Missouri Deceptive Trade Practices Act)

68. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

69. Defendants violated the Missouri Deceptive Trade Practices Act, R.S.Mo. §407.010 et seq. (hereinafter "DTPA"), by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of the Ventralex Hernia Patch.

70. Defendants violated the Missouri DTPA by the use of false and misleading misrepresentations or omissions of material fact in connection with the marketing, promotion, and sale of the Ventralex Hernia Patch.

71. Defendants communicated the purported benefits of the Ventralex Hernia Patch while failing to disclose the serious and dangerous injuries caused by the Ventralex Hernia Patch's memory recoil ring ("PET coil ring") breaking and fragmenting with the intent that consumers, like Mr. Brendel, and his healthcare providers, rely upon Defendants' omissions and misrepresentations.

72. As a result of violating the Missouri DTPA, Defendants caused Mr. Brendel to be implanted with a Ventralex Hernia Patch, causing severe injuries and damages as previously described herein.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

COUNT X

(Negligent Infliction of Emotional Distress)

73. Plaintiffs allege and incorporate by reference each and every allegation contained in this complaint as though fully set forth herein.

74. Plaintiff David Brendel suffered severe emotional distress, which was as a result of Defendants' negligent conduct in designing, developing, testing, inspecting, manufacturing, producing, advertising, marketing, promoting, distributing, and/or selling of the Ventralex Hernia Patch for hernia repair surgery.

75. Mr. Brendel suffered severe emotional distress, which was a result of Defendants' negligent conduct in failing to adequately and safely design and construct an effective and safe Ventralex Hernia Patch for hernia repair surgery.

76. Therefore, Defendants are liable to Mr. Brendel.

77. Defendants' conduct in continuing to market, sell and distribute the

Composix Ventralex Hernia Patch after obtaining knowledge it was failing and not performing as represented and intended, showed complete indifference to or a conscious disregard for the safety of others justifying an award of additional damages for aggravating circumstances in such a sum which will serve to deter Defendants and others from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendants for:

A. A fair and just amount of actual damages in excess of seventy-five thousand dollars ($75,000);

B. A fair and just amount of punitive damages in an amount to deter Defendants and others from like conduct;

C. Costs herein incurred; and

D. Such other and further relief which may in the premises be just and proper.

Demand for Jury Trial

PLAINTIFFS REQUEST A TRIAL BY JURY ON ALL COUNTS.

CAREY, DANIS & LOWE

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